

REMARKS

With entry of this amendment, claims 1, 3-10, 12-20, 22-29, 31-37, 62-64, 66, 69, 71, and 74-95 are pending in the above-identified application. Claims 69, 71, 93 and 94 have been allowed. Claims 64 and 66 are objected to. In view of the remarks below, examination and reconsideration of claims 1, 3-10, 12-20, 22-29, 31-37, 62-64, 66, 74-92, and 95 are respectfully requested.

Rejections under 35 U.S.C. § 103

Houser in view of Lentz

Claims 1, 3-5, 12-20, 22-24, 31-35, 74-77, and 83-90 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Houser *et al.* (U.S. Patent No. 6,149,681, hereinafter "Houser") in view of Lentz *et al.* (U.S. Patent No. 6,428,571, hereinafter "Lentz"). Applicants traverse for the reasons set forth hereinbelow.

Applicants first note that the particular structure recited in the present claims, *inter alia*, "a flap of flexible material comprising a layer that is secured to itself and another layer," has certain technical advantages over a "secured only to itself" arrangement for forming a loop about a transverse member. As seen, for example, in Figure 25A of the present application, elongation of a flap 233 affixed between layer 232 and layer 215 may be opposed by shear loads carried on both major surfaces of the flap itself, which can help reduce or eliminate tension loads on the layer-layer bonds and any associated delamination.

In contrast, if a loop formed from a single "fixed to itself" flap were to deform under a load imposed by the transversely oriented member, any layer-layer bond may gradually change from being loaded in shear to carrying a localized tension load. For example, in Houser, the layer 80 of graft material (*see* Houser at Figure 8) may elongate under a load imposed by compression of the structural layer 78. If the layer 80 elongates more than the "flap" portion 92

folded over the rectangular frame 90, the edge of the bond 94 between portion 92 and layer 80 may be subjected to a concentrated force pulling portion 92 away from the underlying material.

An endovascular graft as recited in the present claims, comprising a loop portion about a transverse member and formed by flap of flexible material comprising a layer that is secured to itself and another layer, is neither taught nor suggested by the cited art. First, the Examiner does not contend, nor can it be reasonably asserted, that either Houser or Lentz by itself teaches or suggests a flap of flexible material comprising "a layer that is secured to itself and another layer." Instead, the Examiner relies on the contention that this limitation would result from a combination of these references. As set forth below, the Examiner has not shown a specific motivation in either Houser or Lentz to combine the references so as to achieve this particular structural feature.

The Examiner states that "[w]hen the two-layered flap of flexible material is folded back to form a loop portion about the transversely oriented member, ... the flap will comprise a layer ... that is secured to itself and another layer" (Office Action dated 3/22/05 at page 4.) Thus, the Examiner appears to assume, without specific support in the cited art, that both layers of a two-layered graft would be utilized in forming a loop as recited in the claims.

To the contrary, if the references were directly combined, per the disclosure actually in the references themselves, they would not result in the structure now being claimed. Instead, per the only looped structure shown, only a single layer of material would be used, and that layer would still be attached only to itself. In fact, even assuming (for arguments sake only) that the cited references can be combined in the manner proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness under 35 U.S.C. § 103. MPEP § 2143.01. The Examiner must show a motivation or suggestion to modify the cited art to meet the claimed invention. *See id.* Here, the Examiner has not shown where either Houser or Lentz would lead one of ordinary skill in the art to use both layers of Lentz's graft for forming the flap

of Houser, especially since, as disclosed by Houser, a single layer is sufficient to secure the rectangular frame to the graft material.

Applicants emphasize that, during the examination process, it is incumbent on the Examiner to avoid the tendency to resort to "hindsight" based on Applicant's disclosure. *See* MPEP § 2142 (stating that "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of facts gleaned from the prior art"). In the present case, for the reasons set forth above, Applicants submit that it is only through hindsight, based on the instant disclosure, that the Examiner can reconstruct the present claims in view of Houser and Lentz.

In view of the above, claims 1, 3-5, 12-20, 22-24, 31-35, 74-77, and 83-90 should be allowable over Houser and Lentz under 35 U.S.C. § 103(a). Withdrawal of the rejection is respectfully requested.

Houser in view of Lentz and Edwin

Claims 6, 25, 37 and 78 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Houser *et al.* and Lentz *et al.* as applied to claims 5, 24, 35 and 77 above, and further in view of Edwin *et al.* (U.S. Patent No. 6,245,099 as cited in previous office action). Applicants traverse.

Because claims 5, 24, 35, and 77 should be allowable for the reasons set forth above with respect to the rejection in view of Houser and Lentz, claims 6, 25, 37, and 78, depending therefrom, should also be allowable. Withdrawal of the rejection is respectfully requested.

Layne in view of Lentz

Claims 62 and 91 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Layne (U.S. Patent No. 6,558,414) in view of Lentz *et al.* Applicants traverse for the reasons set forth hereinbelow.

As noted in Applicants' remarks with respect to Houser and Lentz above, "a flap of flexible material comprising a layer that is secured to itself and another layer" has certain technical advantages over a "secured only to itself" arrangement for forming a loop about a transverse member. To briefly reiterate the example set forth above, elongation of a flap affixed between two layers may be opposed by shear loads carried on both major surfaces of the flap itself, which can help reduce or eliminate tension loads on the layer-layer bonds and any associated delamination. In contrast, if a loop formed from a single "fixed to itself" flap were to deform under a load imposed by the transversely oriented member, any layer-layer bond may gradually change from being loaded in shear to carrying a localized tension load.

For example, the separated longitudinal strips 50 of Layne (*see* Layne at Figure 4) may elongate under a load imposed by the ring members. If these strips elongate more than the underlying material of the tube from which they were cut, the edge of the bond between the strip and the tube may be subjected to a concentrated force pulling the strip away from the underlying tube material.

An endovascular graft as recited in the present claims, comprising a loop portion about a transverse member and formed by flap of flexible material comprising a layer that is secured to itself and another layer, is neither taught nor suggested by Layne in view of Lentz. Again, as with the rejections in view of Houser and Lentz, the Examiner does not contend that either Houser or Lentz by itself teaches or suggests a flap of flexible material comprising "a layer that is secured to itself and another layer," but instead relies on an assertion that this limitation would result from a combination of these references. Again, the Examiner has not shown a

specific motivation in either Layne or Lentz to combine the references so as to achieve this particular structural feature.

The Examiner states that "[w]hen the two-layered flap of flexible material is folded back to form a loop portion about the expandable member, the flap will comprise a layer ... that is secured to itself and another layer" (Office Action dated 3/22/05 at page 6.) Thus, as in the rejections in view of Houser and Lentz, the Examiner appears to assume, without specific support in the cited art, that both layers of a two-layered graft would be utilized in forming a loop as recited in the claims.

Applicants reiterate that if the references were directly combined, per the disclosure actually in the references themselves, they would not result in the structure now being claimed. Instead, per the only looped structure shown, only a single layer of material would be used, and that layer would still be attached only to itself. Again, even assuming (for arguments sake only) that the cited references can be combined in the manner proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness under 35 U.S.C. § 103. MPEP § 2143.01. The Examiner must show a motivation or suggestion to modify the cited art to meet the claimed invention. *See id.* Here, the Examiner has not shown where either Layne or Lentz would lead one of ordinary skill in the art to use both layers of Lentz's graft for forming the flap of Layne. In this regard, Applicants note that, assuming, *arguendo*, a general motivation to combine Layne and Lentz and even if the graft of Layne were to comprise two layers of graft material, because Layne discloses a single layer as being sufficient for folding back over and weaving between adjacent stents to produce the encapsulated stent, there is no particular motivation to use both layers to form the flap as proposed by the Examiner.

In view of the above, claims 62 and 91 should be allowable over Layne and Lentz under 35 U.S.C. § 103(a). Withdrawal of the rejection is respectfully requested.

Layne in view of Lentz and Lombardi

Claim 63 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Layne and Lentz *et al.* as applied to claim 62 above, and further in view of Lombardi (WO 01/58384 A1). Applicants traverse.

Because claim 62 should be allowable for the reasons set forth above with respect to the rejection in view of Layne and Lentz, claim 63, depending from claim 62, should also be allowable. Withdrawal of the rejection is respectfully requested.

Layne in view of Lentz and Edwin

Claim 92 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Layne in view of Lentz *et al.* as applied to claim 91 above, and further in view of Edwin *et al.* Applicants traverse.

Because claim 91 should be allowable for the reasons set forth above with respect to the rejection in view of Layne and Lentz, claim 92, depending from claim 91, should also be allowable. Withdrawal of the rejection is respectfully requested.

Allowable Subject Matter

Applicants appreciate the Examiner's indication that claims 69, 71, 93, and 94 are allowed.

The Examiner has objected to claims 64 and 66 as dependent on a rejected base claim, but has indicated that these claims would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. However, because independent claim 62 (from which claims 64 and 66 depend) should be allowable over the cited

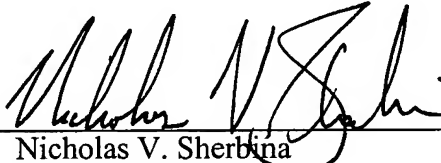
art as set forth above, Applicants decline to amend claims 64 and 66 and instead request reconsideration of the objection.

CONCLUSION

Applicants respectfully request reexamination and reconsideration of the claims in this matter. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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